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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,873	02/18/2004	Casey K. Lee	A-9859A	9492
181	7590	06/02/2006	EXAMINER	
MILES & STOCKBRIDGE PC 1751 PINNACLE DRIVE SUITE 500 MCLEAN, VA 22102-3833			REIMERS, ANNETTE R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

<b>Office Action Summary</b>	<b>Application No.</b> 10/779,873	<b>Applicant(s)</b> LEE, CASEY K.	
	<b>Examiner</b> Annette R. Reimers	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-87 is/are pending in the application.
- 4a) Of the above claim(s) 41 and 59-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-40, 42-58 and 77-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

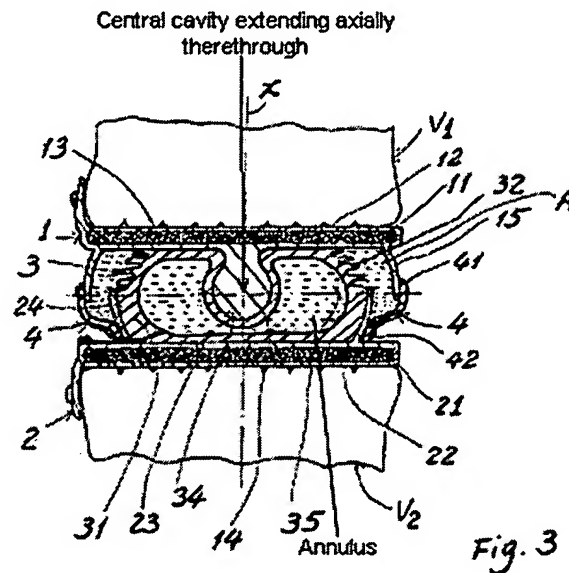
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-35, 38-39, 42-44, 46, 51, 57-58, 77-79, 82-83 and 87 are rejected under 35 U.S.C. 102(e) as being anticipated by Huang (U.S. Patent Number 6,893,465).

Huang discloses a total prosthesis for replacing the entire human intervertebral disk with a polymer core, 3, comprising an annulus, 35, surrounding a central cavity the annulus having upper and lower and side surfaces and a central cavity extending axially therethrough (see figure 3 below), wherein the annulus is made of a first biocompatible material and being shaped and sized to approximate the annulus fibrosus of a natural intervertebral disk, the first biocompatible material being an elastomer having a elastic modulus approximating that of the annulus fibrosus of the natural human intervertebral disk, upper and lower transitional plates, 13 and 23, affixed lower surfaces of the annulus the upper and lower transitional plates being made of a second biocompatible material having a durometer hardness respectively to the upper and greater than that of the first biocompatible polymer and upper and lower endplates, 12 and 22, adapted to

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contact adjacent vertebrae and affixed respectively to the upper and lower transitional plates (see figure 1 and column 3, lines 66-67, and column 4, lines 1-67).



Each of the endplates has an inner surface shaped to contact the outer surface of the transitional plate and each of the endplates has a projection at a posterior edge shaped to form a groove for receiving a posterior edge of a transition plate (see figure 1). Furthermore, each of the transition plates are molded to the upper and lower surfaces of the annulus (see figure 1 ). The cavity is filled with an incompressible liquid (see column 3, lines 49-51). An outer surface of at least one of the endplates is provided with a surface texture adapted for bone ingrowth and at least one of the endplates is provided with a fin, 121, upstanding from the outer surface and extending away from the anterior edge along a lateral midline of the outer surface (see figure 1 and column 2, lines 49-53).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-37, 40, 45, 47-50, 53-56, 80-81 and 84-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Patent Number 6,893,465).

Huang discloses the claimed invention except for first and second elastomeric synthetic polymer having a durometer hardness in a range of about Shore A70 to about Shore A90 and Shore A100 to about Shore D65, respectively, a first elastomeric synthetic polymer having an e-value in a range of about 3-16 megapascals, a cavity having an e-value of about 1-4 megapascals, transition plates have thickness dimension at anterior and posterior edges of about 4-7 mm and 1-3 mm, respectively, the upper and lower endplates having a maximum depth of curvature of about 1.5-2.5 mm and 0.6-2.0 mm, respectively, and the maximum depth of curvature being located at a point spaced from an anterior edge of the endplate by a distance of about 60% of an antero-posterior diameter of the endplate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Huang with all of these features, since it has been held that where the general conditions of a claim

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are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 47, 50 and 52, i.e. the transition plates being dome shaped, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Huang with the transition plates being dome shaped applicant has not disclosed that the transition plates being dome shaped solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a transition plate for a prosthesis. In re Dailey and Eilers, 149 USPQ 47 (1966).

### ***Response to Arguments***

Applicant's arguments filed on March 06, 2006 have been fully considered, but they are not persuasive. Examiner respectfully disagrees with applicant that Huang lacks an annulus having a central cavity extending axially therethrough, since Huang does have an annulus, 35, having a central cavity extending axially therethrough (see figure 3 above).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

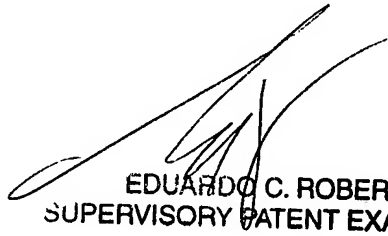
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER